

Practitioner's Docket No. U 015962-1

PATENT

TRANSMITTAL LETTER TO THE U.S. DESIGNATED OFFICE (DO/US)--  
ENTRY INTO THE U.S. NATIONAL STAGE UNDER CHAPTER I

INTERNATIONAL APPLICATION NO. PCT/IN2005/000005	INTERNATIONAL FILING DATE 5 JANUARY 2005	PRIORITY DATE CLAIMED 6 JANUARY 2004, etc
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TITLE OF INVENTION  
CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION COMPRISING AN  
ACID-INSOLUBLE AND A BIOADHESIVE POLYMER

## APPLICANT(S)

1. JAIN, RAJESH
2. JINDAL, KOUR CHAND
3. SINGH, SUKHJEET

Mail Stop PCT  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

ATTENTION: DO/US

COMPLETION OF FILING REQUIREMENTS  
FOR INTERNATIONAL APPLICATION ENTERING NATIONAL  
STAGE IN U.S. DESIGNATED OFFICE (DO/US) UNDER 35 U.S.C. 371

*WARNING: Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date, the application is still considered to be in the international stage. If mailing procedures are utilized to obtain a date, the express mail procedure of 37 CFR 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 CFR 1.8(2)(xi)).*

*NOTE: Documents and fees must be clearly identified as a submission to enter the national stage under 35 USC 371. Otherwise, the submission will be considered as being made under 35 USC 111. 37 CFR 1.494(f).*

## CERTIFICATION UNDER 37 C.F.R. 1.10\*

(Express Mail label number is mandatory.)  
(Express Mail certification is optional.)

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date **February 8, 2007**, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EV 927 568 007 US**, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Geraldine Marti

Type or print name of person mailing paper



Signature of person mailing paper

**WARNING:** Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office (DO/US)  
under 35 USC 371—page 1 of 7) 13-8

(check and complete the following item, if applicable)

☒ This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. 1.494 (FORM PCT/DO/EO/905).

☒ A copy of FORM PCT/DO/EO/905 accompanies this response.

#### DECLARATION OR OATH

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the . . . oath or declaration in order to prevent abandonment of the application . . . . The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."

I. (a) ☒ No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

#### OR

(b) ☐ The declaration or oath that was filed was determined to be defective. A new original oath or declaration is attached.

NOTE: For surcharge fee for filing declaration after filing date, complete item IV(2).

NOTE: Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:

- (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
- (B) serial number and filing date;
- (C) attorney docket number which was on the specification as filed;
- (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
- (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 602, 8<sup>th</sup> ed.

NOTE: Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 CFR 1.10(c).

NOTE: 37 CFR 1.41(a) points out that "Full names must be stated, including the family name and at least one given name without abbreviation together with any other given name or initial."

(complete as applicable)

Attached is a

- (a) ☐ Statement by practitioner that papers attached to declaration are a copy of those filed in PTO to get a filing date
- (b) ☐ Statement that substitute specification contains no new matter.
- (c) ☐ Preliminary Amendment
- (d) ☐ Submission of "Sequence Listing," computer readable copy, and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence

### TRANSMITTAL OF ENGLISH TRANSLATION OF NON-ENGLISH LANGUAGE PAPERS

*NOTE: 37 C.F.R. § 1.4959(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . a translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)). . . . applicant will be so notified and given a period of time within which to file the translation . . . in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of thirty months after the priority date . . . . A 'Sequence Listing' need not be translated if the 'Sequence Listing' complies with PCT Rule 12.1(d) and the description complies with PCT Rule 5.2(b)."*

- II. ☐ Submitted herewith, is a English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 CFR 1.495(c)).

*NOTE: For fee for processing a non-English application, and submission of an English translation later than 30 months after the priority date, complete item IV(3) below.*

*NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR § 1.69(b).*

### FEES

III.

*NOTE: See 37 CFR § 1.28(a).*

I. Fees for search, exam or claims

- ☐ Non-U.S. Search Report filed —\$400.00;  
small entity—\$200.00 \$ \_\_\_\_\_
- ☐ No Search Report —\$500.00; small entity —\$250.00 \$ \_\_\_\_\_
- ☐ Exam Fee not paid to U. S.—\$200.00; small entity—\$100.00 \$ \_\_\_\_\_

- ☐ U. S. Search fee with U.S. WO or IPER conditions not satisfied—\$100.00; small entity—\$50.00 \$ \_\_\_\_\_
- ☐ U. S. Search fee with U.S. WO or IPER conditions satisfied—\$0.00 \$ \_\_\_\_\_
- ☐ Spec and drawing, each 50 pages over 100 37 C.F.R. 1.16(s)—\$250.00 \$ \_\_\_\_\_
- ☐ Each independent claim in excess of 3 (37 CFR 1.492 \$200.00; Small entity—\$100.00) \$ \_\_\_\_\_
- ☐ Each claim in excess of 20 (37 CFR 1.492 - \$50.00; small entity—\$25.00) \$ \_\_\_\_\_
- ☐ Multiple dependent claim(s) (37 CFR 1.492 - \$360.00; small entity—\$180.00) \$ \_\_\_\_\_

2. Surcharge fees

- ☒ Surcharge set forth in § 1.492(e), for accepting the declaration later than 30 months after the priority date in filing an application in the U.S. pursuant to § 1.495(c)— \$130.00; small entity—\$65.00 \$ \$130.00

NOTE: The processing fee in the next item (Number 3) below is not subject to a reduction for small entity status.

3.

- ☐ Processing fee set forth in § 1.492(f), for acceptance of an English translation later than 30 months after the priority date—\$130.00 \$ \_\_\_\_\_

Total fees \$ \$130.00

### SMALL ENTITY STATUS

IV. A statement that this filing is by a small entity

NOTE: See 37 CFR 1.28(a).

(check and complete applicable items)

- a. ☐ is attached.  
☐ was filed on \_\_\_\_\_ (original).  
☐ was made by paying a small-entity basic national filing fee

**WARNING:**

"Small entity status must not be established unless the persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P. Section 509.03, 6th ed., rev. 2, July 1996 (emphasis added).

- b. ☐ A separate refund request accompanies this paper.

## EXTENSION OF TIME

(complete (a) or (b), as applicable)

V.

NOTE: 37 C.F.R. § 1.704(b) "... an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-months period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph."

The proceedings herein are for a patent application. The provisions of 37 C.F.R. § 1.136(a) apply.

(a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below:

	Extension (months)	Fee for other than small entity	Fee for small entity
<input type="checkbox"/>	one month	\$ 120.00	\$ 60.00
<input type="checkbox"/>	two months	\$ 450.00	\$ 225.00
<input type="checkbox"/>	three months	\$ 1,020.00	\$ 510.00
<input type="checkbox"/>	four months	\$ 1,590.00	\$ 795.00

NOTE: The 2-month time period for reply to A Notice to File Missing Parts of an Application is not identified on the Notice as a statutory period subject to 35 U.S.C. 133. Thus, extensions of time of up to 5 months under 37 CFR 1.136(a), followed by additional time under 37 CFR 1.136(b), when appropriate, are permitted. MPEP 710.02(d)(c), 8<sup>th</sup> ed.

☐ five months \$ 2,160.00 \$ 1,080.00

Fee \$ \_\_\_\_\_

If an additional extension of time is required, please consider this a petition therefore.

(check and complete the next item, if applicable)

☐ An extension for \_\_\_\_\_ months has already been secured. The fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.  
Extension fee due with this request \$ \_\_\_\_\_

or

(b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

## TOTAL FEE DUE

VI. The total fee due is:

Completion fee(s)                      \$ \$130.00  
Extension fee (if any)                \$ \_\_\_\_\_

TOTAL FEE DUE                      \$ \$130.00

## PAYMENT OF FEES

VII.

☒ Enclosed is a check in the amount of \$ \$130.00  
☐ Charge Account No. 12-0425 in the amount of \$ \_\_\_\_\_.  
A duplicate of this request is attached.

## AUTHORIZATION TO CHARGE ADDITIONAL FEES

VIII.

**WARNING:**        *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges.*

**NOTE:** "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 CFR 1.136(a)(3).

**NOTE:** "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 CFR 1.26(a).

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper, and during the entire pendency of this application, to Account No. 12-0425.

☒ 37 C.F.R. 1.492(a), (b) or (c) (search or exam fee)  
☐ 37 C.F.R. 1.492 (presentation of extra claims)

**NOTE:** *Because additional fees for excess or multiple dependent claims not paid on filing, or on later presentation, must only be paid, or these claims canceled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.*

☒ Spec and drawing, each 50 pages over 100 37 C.F.R. 1.16(s)  
☒ 37 C.F.R. 1.17 (application processing fees)  
☒ 37 C.F.R. 1.17(a)(1)-(5)(extension fees pursuant to § 1.136(a).

**WARNING:**        *While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a "quest or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).*

**NOTE:** Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application **only after the mailing of the notice of allowance**. Accordingly, general authorizations to any fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL 85-B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1.311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant and submitted, § 1.311(b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b), Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

**NOTE:** 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity

[ ] 37 C.F.R. 1.492(e) and (f) (surcharge fees for filing the declaration and/or an English translation of an international application later than 30 months from the earliest claimed priority date)

**WARNING:** It is suggested that you always check this last authorization.

[X] Refund any overpayment to deposit account 12-0425



SIGNATURE OF PRACTITIONER

Reg. No. 33,778

Janet I. Cord  
(type or print name of practitioner)

Tel. No.: (212)708-1935

\_\_\_\_\_  
P.O. Address

\_\_\_\_\_  
c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023

Customer No.:00140



00140

PATENT TRADEMARK OFFICE



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
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 www.uspto.gov

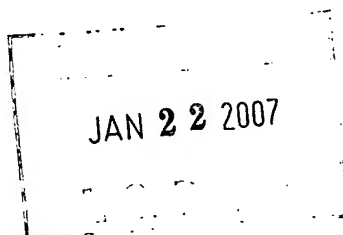
U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/551,058	Rajesh Jain	U 015962-1

INTERNATIONAL APPLICATION NO.
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PCT/IN05/00005

I.A. FILING DATE	PRIORITY DATE
01/05/2005	01/06/2004

140  
 LADAS & PARRY  
 26 WEST 61ST STREET  
 NEW YORK, NY 10023



CONFIRMATION NO. 4104

371 FORMALITIES LETTER



\*OC000000022027919\*

Date Mailed: 01/18/2007

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 09/29/2005
- Copy of the International Search Report filed on 09/29/2005
- Preliminary Amendments filed on 09/29/2005
- Request for Immediate Examination filed on 09/29/2005
- U.S. Basic National Fees filed on 09/29/2005
- Priority Documents filed on 09/29/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of **\$500** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$630** for a Large Entity:



- **\$130** Surcharge.
- Total additional claim fee(s) for this application is \$ **500**
  - **\$500** for **10** total claims over 20.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.  
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

SHAKEEL AHMED

Telephone: (703) 308-9140 EXT 208

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/551,058	PCT/IN05/00005	U 015962-1